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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,918	09/05/2003	Robin M. Forbes Jones	TAV-2044	8375

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EXAMINER

ROE, JESSEE RANDALL

ART UNIT	PAPER NUMBER
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1793

MAIL DATE	DELIVERY MODE
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11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,918

Applicant(s)

FORBES JONES ET AL.

Examiner

Jessee Roe

Art Unit

1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10,12-20,32-34 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10,12-20,32-34 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-2, 4-8, 10, 12-20, 32-34 and 53 are pending wherein claims 1, 5, 6 and 14 are amended; claims 3, 9, 11, 21-31 and 35-52 are canceled; and claim 53 is new.

Status of Previous Rejections

The previous rejections of claims 1-2, 4-8, 10, 12, 16-20 and 32-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the Applicant's amendments to the claims. The previous rejection of claims 13-14 under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542), and further in view of Thielemann (US 3,241,954) are withdrawn in view of the Applicant's arguments. The previous rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542), and further in view of Crook (US 4,353,742) is withdrawn in view of the Applicant's arguments.

Status of Previous Objections

The previous objection to claim 14 is withdrawn in view of the Applicant's amendment to the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-8, 10, 12, 16-20 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542).

Claims 1-2, 4-8, 10, 12, 16-20 and 32-34 are rejected on the same grounds set forth in the Office Action of 27 February 2007.

In regards to the amended features of claim 1 which recite "at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium;" and "no greater than 0.035 weight percent carbon", Smith ('542) discloses adding 0 to 2 weight percent aluminum in the (col. 5, lines 3-10) and no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11) that would form a wire or cable (col. 3, lines 64-75).

In regards to the amended feature of claim 5 which omits the limitation of "no greater than 0.035 weight percent carbon", the Examiner notes that the instant invention would not necessitate the addition of manganese, phosphorus, or silicon because "no greater than" includes 0 weight percent.

In regards to the amended feature of claim 6, the Examiner notes that the amendment would not change the scope of the claim.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Smith (US 3,356,542) as applied to claim 1, and further in view of Ototani et al. (US 4,820,485).

In regards to claims 13-15, Smith ('542) discloses a cobalt-based alloy, but Smith ('542) does not specify wherein the alloy would contain 5 to 20 ppm calcium (claim 13), 5 to 50 ppm calcium (claim 14), or 5 to 50 ppm cerium.

Ototani et al. ('485) disclose adding 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium) to a cobalt-, nickel-, or iron-based alloy in order to perform deoxidation, desulfurization, and denitrification of the alloy (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add 5 to 100 ppm calcium and 0 to 200 ppm rare earth element (cerium), as disclosed by Ototani et al. ('485), to the cobalt-based alloy as disclosed by Smith ('542), in order to perform deoxidation, desulfurization, and denitrification of the alloy, as disclosed by Ototani et al. ('485) (col. 7, line 65 – col. 8, line 60 and col. 10, lines 45-57).

Claims 20 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as applied to claim 1, and further in view of Thompson (US 6,342,068).

In regards to claims 20 and 32-34, Smith ('542) discloses a cobalt-based alloy that would be used as a wire or cable, but Smith ('542) does not specify that the cobalt-based alloy would be used as a stent (surgical implant device).

Thompson ('068) discloses that cobalt-based alloys would be used as stents because of their biocompatibility, fatigue resistance, and corrosion resistance (col. 6,

lines 21-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the cobalt-based alloy, as disclosed by Smith ('542), as a stent, as disclosed by Thompson ('068), because cobalt-based alloys would have biocompatibility, fatigue resistance, and corrosion resistance, as disclosed by Thompson ('068) (col. 6, lines 21-34).

Still regarding claim 34, the Examiner asserts that the alloy disclosed by Smith ('542) would meet the ASTM standard specification F 562, because Smith ('542) discloses substantially the same alloy composition as that of the instant invention.

In regards to claim 53, Smith ('542) discloses an alloy having favorable fatigue resistance (col. 1, line 62 – col. 2, line 14). A comparison of the alloy disclosed by Smith ('542) in comparison with that of the instant invention is shown in the table on the following page.

Element	From Instant Claims (weight percent, except N)	Smith ('542) (weight percent)	Overlapping range
Claim 1 (col. 4, line 23 – col. 5, line 11)			
Co	at least 20	at least 25	at least 25
Ni	32.7-37.3	5-45	32.7-37.3
Cr	18.75-21.25	13-25	18.75-21.25
Mo	8.85-10.65	7-16	8.85-10.65
N	less than 30 ppm	0-0.05	0-30 ppm
Ti	less than 0.7	0-2.0	0-less than 0.7
Al	at least 0.05 – 0.15	0-2.0	0.05-2.0
Fe	less than 1.05	0-6.0	0-less than 1.05

Still regarding claim 53, the Examiner notes that the instant invention would not necessitate the addition of manganese, phosphorus, or silicon because “no

greater than” includes 0 weight percent. Smith ('542) discloses adding no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the cobalt-based alloy (col. 4, line 23 – col. 5, line 11).

The ranges disclosed by Smith ('542) for cobalt, nickel, chromium, molybdenum, nitrogen, titanium, aluminum, and iron are within the ranges claimed of the instant invention. The Examiner notes that the disclosed composition of the alloy overlaps with the composition of the claimed invention. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the compositions disclosed by Smith ('542) because Smith ('542) discloses the same utility (alloy wire) throughout the disclosed ranges (col. 3, lines 64-75).

Still regarding claim 53, Smith ('542) does not specify wherein the alloy would include spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the composition of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 – col. 5, line 11). . Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42, col. 5, lines 11-30). Therefore, in absence of evidence to the contrary, it would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. See MPEP 2112.01 I.

Response to Declaration

The Declaration filed under 37 CFR 1.132 filed 24 August 2007 is sufficient to overcome the rejection of claims 13-14 based upon 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542), and further in view of Thielemann (US 3,241,954). The Declaration filed under 37 CFR 1.132 filed 24 August 2007 is also sufficient to overcome the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542), and further in view of Crook (US 4,353,742).

The Declaration filed under 37 CFR 1.132 filed 20 September 2007 is insufficient to overcome the rejection of claims 1-2, 4-8, 10, 12, 16-20 and 32-34 based upon 35 U.S.C. 103(a) as being unpatentable over Smith (US 3,356,542) as set forth in the last Office action because:

First, the Declaration filed 20 September 2007 is not commensurate in scope with the claims because the Declaration filed 20 September 2007 is directed toward a wire whereas the independent claims are directed toward merely an alloy composition. MPEP 716.03(a).

Second, in the Declaration filed 20 September 2007, the Applicant declares "As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications." In response, the Examiner notes that Applicant has not provided any factual evidence to substantiate this opinion. MPEP 716.01(c) (I) and 716.01(c) (III).

Third, in the Declaration filed 20 September 2007, the Applicant declares "I do not base this conclusion only on the substantial, rapid, and continuing increase in FWM's sales of 35N LT wire and on the fact that 35N LT wire has largely displaced other available biocompatible alloys for use in several surgical applications. I also base this conclusion on direct feedback from customers for 35N LT for use in certain surgical implant applications - those customers state that they chose FWM's 35N LT wire over wire formed from other available alloys because of the FWM product's superior fatigue resistance." In response, the Applicant's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention; the Applicant has not shown whether or not the sales of the 35N LT wire were based on heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the instant invention; and the commercial success of the 35N LT wire may have been attributable to extensive advertising and position as a market leader before the introduction of the patented product. MPEP 716.03(b) (I). Also, gross sales figures do not show commercial success absent evidence as to market share. MPEP 716.03(b)(IV).

Response to Arguments

Applicant's arguments filed 24 September 2007 have been fully considered but they are not persuasive.

First, the Applicant primarily argues that Smith ('542) does not describe an alloy including less than 30 ppm nitrogen, as claimed in the instant invention. In response, the Examiner notes that Smith ('542) does not disclose a motivation to only use nitrogen from the group consisting of carbon, boron, oxygen, nitrogen, or beryllium and the lower limit of these compositions within the alloy would be 0 weight percent. MPEP 2144.08 (II)(4)(a). One of ordinary skill could envisage selecting one or more of carbon, boron, oxygen, or beryllium.

Second, the Applicant primarily argues that wire formed from the alloy of the present invention withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that that the scope of independent claims 1 and 53 are directed to an alloy and not a wire and the scope of the dependent claims do not limit the scope of the alloy to a wire. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Third, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Roy V. King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JR


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